## SECTION 15

## SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

**1. Submitter's name, address, telephone number, contact person, and date summary prepared;**

a. Submitter: STAAR Surgical Company
1911 Walker Ave.
Monrovia, CA 91016
(626) 303 7902

b. Contact Person: Herb Crane

c. Date Summary Prepared: February __, 2002

**2. Name of device, including trade name and classification name:**

a. Trade/Proprietary Name: Surge-free Aspiration Adapter

b. Classification Name: Unit, Phacofragmentation

**3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Predicate Device Identification Table

| Product Name | Company Name | 510(k) # - Clearance Date |
|---|---|---|
| Vacuum Surge Suppresser (VSS) | Surgin Surgical Instrumentation | K950600 - 5/10/95 |
| PhacoGard | Syntec Inc. | K002932 – 1/4/01 |
| Automated Chamber Maintenance (ACM) Module | Paradigm Medical | K971795 – 7/14/97 |

## 4. Description of Device:

The Surge-free Aspiration Adapter is a filter protected flow restriction device intended to be placed between the handpiece and aspiration tubing used during phacoemulsification surgery. The Surge-free Aspiration Adapter prevents/neutralizes vacuum surges in the aspiration line resulting from the sudden clearing of occlusions.

## 5. Statement of intended use:

The Surge-free Aspiration Adapter is a filter protected flow restriction orifice used during cataract surgery to prevent/neutralize vacuum surges in the aspiration line

## 6. Summary of technological characteristics compared to predicate devices:

The table below illustrates how the technological characteristics of the Surge-free Aspiration Adapter compares to the predicate device.

Technological Characteristic Comparison Table

| Characteristic | Surge-free Aspiration Adapter | Vacuum Surge Suppresser (VSS) K950600 |
|---|---|---|
| Placement | In aspiration line adjacent to handpiece | In aspiration line adjacent to handpiece |
| Materials | Silicone/Teflon | Silicone/Teflon |
| Sterilization | Steam | Gamma/Steam |
| Effect of device | Reduction in vacuum surges resulting from release of aspiration tubing occlusions | Reduction in vacuum surges resulting from release of aspiration tubing occlusions |
| Mode of Operation | Vacuum surges are minimized by use of a restrictive bore connector. The restrictive bore is protected from occlusion itself by a Teflon mesh. | Vacuum surges are minimized by use of a collapsible chamber connecting two tubing sections. |
| Single Use or Reusable | Single Use | Single Use and Reusable |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2002

Mr. Herb Cane
Director RA
STAAR Surgical Co.
1911 Walker Ave.
Monrovia, CA 91016

Re: K020734
Trade/Device Name: Surge-free Aspiration Adapter
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: II
Product Code: HQC
Dated: March 4, 2002
Received: March 6, 2002

Dear Mr. Cane:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

## SECTION 6

## INDICATIONS FOR USE

The Surge-free Aspiration Adapter is a filter protected flow restriction orifice used during cataract surgery to prevent/neutralize vacuum surges in the aspiration line.

Daryl L. Kaufman

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020734

Prescription Use K020734
(Per 21 CFR 801.109)